PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference MLC/FM/2676PC	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/GB2004/003101	International filing date *(day/month/year)* 19.07.2004	Priority date *(day/month/year)* 19.07.2003

International Patent Classification (IPC) or national classification and IPC
C08L67/04, A61L17/12, A61L27/18, A61L27/58, A61L27/54, A61L31/06, A61L31/14

Applicant
SMITH & NEPHEW PLC et al.

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
12.04.2005	30.06.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Telephone No. +49 89 2399-

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/003101

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:

   ☐ international search (under Rules 12.3 and 23.1(b))
   ☐ publication of the international application (under Rule 12.4)
   ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-9 as originally filed

Claims, Numbers

1-37 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

   ☐ the description, pages
   ☐ the claims, Nos.
   ☐ the drawings, sheets/figs
   ☐ the sequence listing *(specify)*:
   ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

   ☐ the description, pages
   ☐ the claims, Nos.
   ☐ the drawings, sheets/figs
   ☐ the sequence listing *(specify)*:
   ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/003101

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-6, 9-12, 17, 24, 25, 28-30
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-37
Industrial applicability (IA)	Yes:	Claims	1-37
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Section V

The following documents are taken into consideration:

D1: US-A-4 968 317 (TOERMAELAE PERTTI ET AL) 6 November 1990 (1990-11-06)
D2: US-B-6 315 7881 (ROBY MARK S) 13 November 2001 (2001-11-13)
D3: US-A-4 700 704 (JAMIOLKOWSKI DENNIS D ET AL) 20 October 1987 (1987-10-20)
D4: US-A-4 559 945 (SHALABY SHALABY W ET AL) 24 December 1985 (1985-12-24)
D5: OKUZAKI H ET AL: "MECHANICAL PROPERTIES AND STRUCTURE OF THE ZONE-DRAWN POLY(L-LACTIC ACID) FIBERS" JOURNAL OF POLYMER SCIENCE, POLYMER PHYSICS EDITION, JOHN WILEY AND SONS. NEW YORK, US, vol. 37, no. 10, 1999, pages 991-996, XP001147427 ISSN: 0887-6266

1. Novelty

The present invention relates to glycolic acid copolymer having a tensile strength of at least 1100MPa.

1.1. Document D1 describes resorbable copolymers which show a high mechanical strength of 1000 to 1500MPa and an elastic modulus of 20 to 50GPa (cf. D1, col.5, l.1 to 12). In Table 1 of D1 a list of resorbable copolymers is given including copolymers of glycolide which can be applied to the orientation process of the invention in order to achieve the fibrillated, high strength material. In addition, in example 3 it is mentioned that glycolide/lactide copolymer (87/13) after being subjected to a drawing operation, has a tensile strength of 550MPa.
The copolymer of D1 is used as medical implant and device in the form of rods, plates, screws, nails and clamps (cf. D1, col. 6, l.53-64).
Hence, D1 takes away novelty of claims 1-6, 9-12, 17, 24, 25, 28, 29, and 30.

1.2. Glycolic acid copolymers including copolymers of glycolide and lactide (cf. D2, col.4, l.16-20), copolymers of glycolide and ϵ-caprolactone (cf. D3, col.2, l.23-26) and copolymers of glycolide and propylene malonate (cf. D4, examples 3 to 5) are well known biodegradable materials used in biomedical applications.

Said copolyesters are spun into fibers followed by quenching and drawing (cf. D2, Fig.5; D3, example XIII; D4, col.7, l.20 to col.8, l. 22).
Since on the one hand, the starting material of the prior art is identical to the copolymer used in the present invention and since on the other hand the manufacturing process of D2 to D4 is very similar to that mentioned in the present application, the person skilled in the art would assume that the resulting copolyester would have similar physical properties. However, the tensile strength of the prior art copolymers is not as high as the tensile strength of the claimed copolymers. Since the application failed to indicate and to define which technical features (e.g. nature and composition of the copolymer, molecular weight thereof, method of preparation) are in fact responsible for achieving the desired high tensile strength, no clear differentiating technical features can be determined between the present invention and the above-mentioned prior art documents. Accordingly documents D2, D3 and D4 might become relevant with regard to novelty.

2. Inventive Step
The problem underlying the present invention is to provide a polymeric composition comprising glycolic acid copolymers with high tensile strength and high tensile modulus.

Document D5 is considered as the nearest prior art document because it is directed to the production of high modulus and high strength poly L-lactic acid (PLLA) fibers and suggests different methods for producing fibers with high tensile modulus and strength including zone-drawing. D5 differs from the present invention in the polymeric fiber material applied in the manufacturing process. Since according to D1 copolymers of glycolide and PLLA are known resorbable polymeric materials which exist in partially crystalline form (cf.D1, Table 1), there is no restraint in preparing high strength fibers starting from glycolic acid copolymers instead of PLLA.
Hence in the light of the combined teaching of D5 and D1, no inventive merit can be acknowledged.